

**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

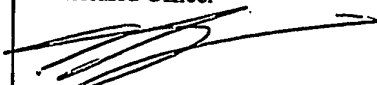
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(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 35557WOP00	<b>FOR FURTHER ACTION</b>	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. <b>PCT/AU2003/000820</b>	International Filing Date (day/month/year) 27 June 2003	Priority Date (day/month/year) 27 June 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. <sup>7</sup> A61K 035/78; A61P 15/00		
Applicant CHINESE MEDICINES SCIENTIFIC CONSULTANTS PTY LTD et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
  - This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of    sheet(s).
3. This report contains indications relating to the following items:
  - I     Basis of the report
  - II    Priority
  - III    Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV    Lack of unity of invention
  - V     Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI    Certain documents cited
  - VII    Certain defects in the international application
  - VIII    Certain observations on the international application

Date of submission of the demand 13 January 2004	Date of completion of the report 27 January 2004
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  <b>MICHAEL GRIEVE</b> Telephone No. (02) 6283 2267

**I. Basis of the report**

1. With regard to the elements of the international application:\*
- the international application as originally filed.
- the description, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- the claims, pages , as originally filed,  
pages , as amended (together with any statement) under Article 19,  
pages , filed with the demand,  
pages , received on with the letter of
- the drawings, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- the sequence listing part of the description:  
pages , as originally filed  
pages , filed with the demand  
pages , received on with the letter of
2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.  
These elements were available or furnished to this Authority in the following language which is:
- the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).
3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished
4.  The amendments have resulted in the cancellation of:
- the description, pages
- the claims, Nos.
- the drawings, sheets/fig.
5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1 to 34	YES
	Claims	NO
Inventive step (IS)	Claims 1 to 34	YES
	Claims	NO
Industrial applicability (IA)	Claims 1 to 34	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

D1: WO 2000/025801A

NOVELTY (N)

The present invention relates to a composition for treating or alleviating a symptom resulting from a gynaecological disorder, comprising the herbs:

- Chi Shao (Paeonia obovata, Root)
- Dang Gui (Angelica Polymorpha, Root)
- Chuan Xiong (Ligusticum Wallichii, Root)
- Xiang Fu (Cyperus Rotundus, Rhizome)
- Yan Hu Suo (Corydalis turtschaninovii, Rhizome)
- Tao Ren (Prunus persica, Seed)

or parts thereof.

Document D1 is merely considered to disclose the general state of the art. This document relates to herbal compositions for the treatment of gastrointestinal disorders, but does not comprise all of the herbs listed above, as required by the present composition.

INVENTIVE STEP (IS)

Claims 1 to 34 - see the comments under novelty above.

**Box No. VIII (iv) DECLARATION: INVENTORSHIP (only for the purposes of the designation of the United States of America)**  
*The declaration must conform to the standardized wording provided for in Section 214; see Notes to Boxes Nos. VIII, VIII (i) to (v) (in general) and the specific Notes to Box No. VIII (iv). If this Box is not used, this sheet should not be included in the request.*

Declaration of inventorship (Rules 4.17(iv) and 51 bis.1(a)(iv)) for the purposes of the designation of the United States of America:

I hereby declare that I believe I am the original, first and sole (if only one inventor is listed below) or joint (if more than one inventor is listed below) inventor of the subject matter which is claimed and for which a patent is sought.

This declaration is directed to the international application of which it forms a part (if filing declaration with application).

This declaration is directed to international application No. PCT/AU03/00820 (if furnishing declaration pursuant to Rule 26ter).

I hereby declare that my residence, mailing address, and citizenship are as stated next to my name.

I hereby state that I have reviewed and understand the contents of the above-identified international application, including the claims of said application. I have identified in the request of said application, in compliance with PCT Rule 4.10, any claim to foreign priority, and I have identified below, under the heading "Prior Applications," by application number, country or Member of the World Trade Organization, day, month and year of filing, any application for a patent or inventor's certificate filed in a country other than the United States of America, including any PCT international application designating at least one country other than the United States of America, having a filing date before that of the application on which foreign priority is claimed.

Prior Applications:

I hereby acknowledge the duty to disclose information that is known by me to be material to patentability as defined by 37C.F.R. § 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the PCT international filing date of the continuation-in-part application.

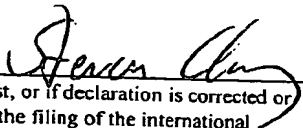
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name: Steven Walter CLAVEY

Residence: Victoria, Australia  
 (city and either US state, if applicable, or country)

Mailing Address: 129 Rowell Avenue, Camberwell, Victoria 3124, Australia

Citizenship: US

Inventor's Signature:   
 (if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent)

Date: 4 August 2003  
 (of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)

Name:

Residence:  
 (city and either US state, if applicable, or country)

Mailing Address:

Citizenship:

Inventor's Signature: \_\_\_\_\_  
 (if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent)

Date: \_\_\_\_\_  
 (of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)

This declaration is continued on the following sheet, "Continuation of Box No. VIII (iv)".

# INTERNATIONAL SEARCH REPORT

International application No.  
**PCT/AU03/00820**

**A. CLASSIFICATION OF SUBJECT MATTER**

Int. Cl. <sup>7</sup>: **A61K 35/78, A61P 15/00**

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
**MEDLINE, DWPI, Traditional Ecological Knowledge Database; Keywords; chi shao, paeonia obovata, peony root, white peony, dang gui, dong quai, angelica polymorpha, chuan xiong, ligusticum wallichii, levisticum, xiang fu, cyperus rutundus, nut grass, coco grass, cocco grass, yan hu suo, corydalis turtchaninovii, tan ren, prunus persica, peach**

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 00/25801 A (Chinese Medicines Scientific Consultants) 11 May 2000 Entire Document	1-34

Further documents are listed in the continuation of Box C       See patent family annex

- |   |   |
|---|---|
| <p>* Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> | <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&amp;" document member of the same patent family</p> |
|---|---|

Date of the actual completion of the international search  
**14 August 2003**

Date of mailing of the international search report  
**18 AUG 2003**

Name and mailing address of the ISA/AU  
**AUSTRALIAN PATENT OFFICE  
PO BOX 200, WODEN ACT 2606, AUSTRALIA  
E-mail address: pct@ipaaustralia.gov.au  
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Authorized officer  
**TERRY SUMMERS**  
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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU03/00820

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report	Patent Family Member					
WO 200025801	AU	200015001	CA	2389993	EP	1126862
	US	6039954				
END OF ANNEX						